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Pilot, Double-Blind, Placebo-Controlled, Parallel Group Study of the Safety and Clinical Activity of CCX282-B in Patients with Moderate to Severe Crohn's Disease

Submission date
13/09/2005

Registration date
21/12/2005

Last Edited
11/01/2021

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Digestive System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00102921

Secondary identifying numbers
CL003_282_b

Study information

Scientific Title
Pilot, Double-Blind, Placebo-Controlled, Parallel Group Study of the Safety and Clinical Activity of CCX282-B in Patients with Moderate to Severe Crohn’s Disease

Acronym
CCX

Study objectives
The purpose of this research study is to investigate the effects of an investigational medication, called CCX282-B, on safety and on some of the symptoms of Crohn’s Disease in patients who are experiencing an active flare-up of moderate to severe Crohn’s Disease

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Crohn's Disease

Interventions
An investigational medication, called CCX282-B (capsules), compared to placebo

Intervention Type
Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)
CCX282-B

Primary outcome measure
The primary immunologic and clinical activity objective of this study is to provide pilot information regarding the immunologic and clinical activity of daily oral doses of CCX282-B in the treatment of moderate to severe Crohn’s Disease, based on changes in the Crohn’s Disease Activity Index (CDAI).

Secondary outcome measures
Secondary immunologic and clinical activity objectives include evaluation of the effect of CCX282-B on the Inflammatory Bowel Disease Questionnaire (IBDQ) instrument, C-reactive protein (CRP), the endoscopic appearance and biopsy of the colon and terminal ileum, and markers of leukocyte subsets and activation status.

Overall study start date
01/08/2004

Completion date
01/02/2006

Eligibility

Key inclusion criteria
1. Diagnosis of moderate to severe Crohn's Disease in small intestine; disease must be active at the time of study entry
2. Use of adequate and approved methods of birth control throughout the study period
3.
Willing and able to sign an informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
70

Key exclusion criteria
1. Pregnant or breastfeeding
2. Infection with hepatitis B, hepatitis C, or human immunodeficiency virus (HIV; the virus that causes AIDS)
3. Abuse of alcohol or of illegal drugs

Date of first enrolment
01/08/2004

Date of final enrolment
01/02/2006

Locations

Countries of recruitment
Netherlands

Study participating centre
Meibergdreef 9
Amsterdam
Netherlands
1105 AZ

Sponsor information

Organisation
ChemoCentryx (USA)

Sponsor details
850 Maude Avenue
Mountain View
United States of America
CA 94043
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pbekker@chemocentryx.com

Sponsor type
Industry

Website
http://www.chemocentryx.com/

ROR
https://ror.org/04gp12571

Funder(s)

Funder type
Industry

Funder Name
ChemoCentryx

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration